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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,409	KIEFFER ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36,38-40,43-55 and 71-86* is/are pending in the application.

4a) Of the above claim(s) *1-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-36,38-40,43-55 and 71-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Note

It is noted that Applicant has filed a notice of appeal and responded to the non-final Official Action of 8/10/04 under 37 CFR 1.116, which is directed to filing after-final amendments. However, the Official Action of 8/10/04 is not final. Therefore, although Applicant may appeal, having had their claims twice-rejected, this is a standard Official Action, and Applicant's amendments and arguments are entered.

Applicant's response and amendments of 2/14/05 are entered.

Claims 37, 41-42, 45-46, and 56-70 are cancelled.

Claims 31, 38-40, 43, and 54 are amended.

Claims 71-86 are newly presented.

Claims 1-30 remain withdrawn as being drawn to non-elected inventions.

Claims 31-36, 38-40, 43-44, 47-55, and 71-86 are presently considered.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

In light of Applicant's cancellation of Claims 37, 41-42, and 45-46, the rejections of those claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, are rendered moot, and thus are withdrawn.

In light of Applicant's arguments and amendments of 2/14/05, the rejections of Claim 43-44, under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for reasons of record in the Official Action of 8/10/04, pp. 2-3, paragraph bridging, for lacking written description with regard to functional variants and subsequences of glucose-dependent insulinotropic polypeptide (GIP) promoter, is withdrawn.

Claims 31-36, 38-40, 43-44, and 47-55 remain rejected, and Claims 71-86 are newly rejected, under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for reasons of record in the Official Action of 8/10/04, pp. 3-4 (referring to the nutrients that increase the production, expression, or secretion of the protein), and the Official Actions of: 8/10/04; pp. 2-10; 12/18/03, pp. 3-4; and 12/18/02, pp. 3-5 (referring to the functional variants and subsequences of any gut endocrine promoter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that Applicant's have amended the independent claims to replace the word "nutrient" with "sugar, carbohydrate, starch, polypeptide, amino acid or fat"; however, such genera are not read in a vacuum, but in the context of the members of each genera that induce the production (which is the increase of the secretion of the protein of interest in cells) of the insulin or leptin encoded by the nucleic acid sequence transforming the cells (independent claims 31 and 71). Hence, for reasons of record, the structure of each of these genera could not be distinguished from each other, much less the broader genera of any sugar, any carbohydrate, any starch, any polypeptide, any amino acid, or any fat. (Official Action of 8/10/04, pp. 3-4).

Response to Arguments – Written Description

Applicant's arguments of 2/14/05 have been fully considered, but are not found persuasive.

Applicant argues that the law does not require a disclosure of every member of each genera, and therefore, the claimed genera of sugar, carbohydrate, starch, polypeptide, amino acid, fats, and gut endocrine promoter variants and subsequences are not required (Applicant's argument of 2/14/05, p. 8, paragraph 3). Moreover, Applicant argues that the various members disclosed (glucose and vitamin D) and those known in the art provides adequate written description to determine that Applicant had possession of the presently claimed genera (Id., pp. 8-9, paragraph bridging).

Such is not persuasive. Applicant's disclosure is limited in each case, to the point where the various members could not be distinguished from each other or the broader genera to which they belong (i.e., sugars, carbohydrates, etc.), and therefore possession is not shown by "description of sufficient, relevant, identifying characteristics" so that the Artisan would recognize that the inventor has possession of the claimed invention, as per Applicant's quoted law (Id.). In fact, Applicant has defined that the sugars, carbohydrates, starches, polypeptides, amino acids, and fats increase production by either increasing the expression or secretion of the protein encoded by the nucleic acid that has transformed the cell (SPECIFICATION, p. 19, paragraph 2; Official Action of 8/10/04, p. 3, paragraph 4). Applicant's disclosure of particular members of any genera that increase the expression of the polypeptide are limited to glucose-inducible elements, the vitamin D response element, metallothionein gene promoter (metals), and beta galactosides (SPECIFICATION, pp. 17-18, Official Action of 8/10/04, paragraph 4).

Applicant's disclosure of such sugars, carbohydrates, starches, polypeptides, amino acids, and fats that increase the secretion of insulin or leptin is limited to a functional description of any thing that causes it to be secreted, e.g., through secretory vesicles (SPECIFICATION, p. 19, paragraph 2; Official Action of 8/10/04, p. 3, paragraph 4). Hence, such sparse disclosure is not considered sufficient to demonstrate the sufficient, relevant, identifying characteristics of any of the various sugars, carbohydrates, starches, polypeptides, amino acids, and fats, such that they would be distinguished from any member of the genera that does not cause production of the same insulin or leptin claimed in the independent claims.

Applicant's arguments with regard to Claims 43-44 are noted, but not addressed in light of the withdrawal of the rejection with regard to the promoters, variants and subsequences thereof, as given above.

Enablement

In light of the cancellation of Claims 37, 41-42, and 45-46, the rejections of such claims under 35 USC 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record in the prior Official Actions, are rendered moot, and thus are withdrawn.

Claims 31-36, 38-40, 43-44, and 47-55 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for A method of treating a mammal having diabetes due to a loss of pancreatic beta, insulin-secreting, cells, comprising contacting duodenal mucosal tissue cells in the mammal transformed with an FIV vector comprising a transgene encoding human insulin, operably linked to the rat GIP promoter, which cells were transformed by intra-luminal incubation of the duodenum, with a sugar that induces production of the insulin by the transformed cells, such contacting by administration of glucose, orally,

thereby causing release of insulin the blood and treatment of the diabetes in a prophylactic manner, does not reasonably provide enablement for treating any subject, any disorder treatable by producing insulin in any mucosal tissue, any gut endocrine promoter, any carbohydrate, any starch, any polypeptide, any animo acid, any fat, or any method of transforming the subject, for reasons of record in the prior Official Actions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 71-68 are newly-rejected, for reasons necessitated by the amendments, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a mouse obesity in a ob/ob mouse comprising implanting GC-1pSwitch cells as described in the Kieffer declaration, peritoneally, and RU486 pellets, subcutaneously, does not reasonably provide enablement for treating any subject, any disorder treatable by producing leptin in any gut or gastrointestinal mucosal cell, any gut endocrine promoter, any carbohydrate, any starch, any polypeptide, any amino acid, any fat, or any method of transforming the subject, or any animal at risk of a disorder, for reasons of record in the previous Official Actions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is now subject to a scope of enablement, in light of the now-limited nature of the transgene which is to be expressed.

Applicant should note that although Claims 31-36, 38-40, 43-44, and 47-55 may now be subject to a scope of enablement, by amending the claims to meet the aforementioned scopes, the Examiner believes a new matter rejection may be applied.

Response to Arguments – Enablement

Applicant's arguments filed on 2/14/05 have been fully considered but are not found persuasive.

Applicant reiterates the arguments concerning that the claims do not encompass gene therapy and that the rejections are based solely on the lack of reasonable predictability in gene therapy (Applicant's response of 2/14/05, p. 15, paragraph 4-p. 16, paragraph 2).

Such is not persuasive, for reasons of record (e.g., Official Action of 8/10/04, p. 11, paragraph 3-p. 12, paragraph 2). Also, the rejection is not based solely on the lack of reasonable predictability in gene therapy, but a considered analysis of the Wands factors (e.g., Official Action of 8/10/04, pp. 10-11, paragraph bridging).

Applicant argues that the Kieffer declaration corroborates that any polynucleotide, including leptin, can be introduced into mucosal tissue cells, and sufficient protein produced therefrom, to provide *in vivo* treatment (Applicant's argument of 2/14/05, p. 16, last paragraph).

Such is not persuasive. Applicant's provided declaration provides a specific type of transformation of cells *in vitro*, which are then introduced into the peritoneal cavity, and further requires subcutaneous administration of RU486, to provide activation of the expression of the genes and subsequent treatment of obese mice. There is no evidence of record that any method of transformation may be used, any method of administration, any animal suffering from any disorder treatable by leptin, any animal at risk of any disorder treatable by leptin, or any evidence

that any particular compound increases secretion of the leptin, when administered by any method. Such arguments are provided, *inter alia*, in the Official Action of 12/18/02, pp. 12-13.

Applicant argues that the Cheung declaration previously submitted (Exhibits 1-2), provides evidence of stable incorporation into mucosal tissues of insulin, DsRed, and GFP transgenes, through administration of AAV and FIV vectors, and therefore, supports the methods of *in vivo* gene delivery (Applicant's argument of 2/14/05, p. 17, paragraph 1).

Applicant's argument is persuasive for the administration of insulin, as reflected in the newly provided scope of enablement; however, this evidence alone does not support any method of administration, any disorder, prophylactic treatment, or any compound that induces production of the protein, as these are directed to intraduodenum administration, constitutive promoters, and no evidence of any treatment (e.g., Official Action of 8/10/04, pp. 13-14). Moreover, this evidence does not support any leptin treatments, as leptin is different from insulin and GFP and DsRed, and it is not reasonably predictable from these results that leptin-encoding vectors, administered by any method would provide for any particular treatment (Id.).

Applicant argues that the Cheung declaration of 2/14/05, which demonstrates the intraluminal-lumenal administration of FIV vectors delivering insulin or SEAP, driven by the GIP or chromogranin A promoter, to mice, and subsequent destruction of the pancreatic beta-cells, demonstrates enablement for the claimed methods (Applicant's argument of 2/14/05, pp. 17-18).

Such is not considered persuasive. Applicant's methods demonstrate a particular method of administration, particular vectors, particular promoters, and subsequent destruction of the beta-cells, but the specification fails to provide the direction and guidance that the Artisan would

require to reasonably predict these methods, as they do not disclose the specific vectors and methods of administration used. As such, Applicant's post-filing-date evidence is not considered enabling.

Further elaboration on the prior enablement rejections

Moreover, with regard to all of Applicant's evidence, such evidence is limited to specific mice strains, and the only demonstration of therapeutic effect is in mice (Cheung declaration of 2/14/05) for the insulin-encoding polypeptides and in ob/ob mice for the leptin-encoding polypeptides (Keiffer declaration of 6/20/03). Moreover, the conditions which the mice are susceptible to with regard to the insulin treatment is STZ induced destruction of pancreatic beta-cells, which is not a real world condition to which an animal is susceptible, and does not reasonably predict treatment of animals already susceptible to any real-world disease, as animals are not generally considered susceptible to diabetes through SZT exposure, and no art of record provides evidence that such methods may be extrapolated to other causes of diabetes. As such, these are not the real world uses to which Applicant contemplates, which encompass treating humans. Indeed, the specification makes clear that Applicant desires to treat humans (e.g., pp. 1-4). However, such models are not reasonably predictable of treatment of humans, or indeed other animals.

For example, with leptin, the increase in leptin would not be predicted to treat any form of obesity, as obese children already express increased levels of leptin (Shalitin, et al. (2003) Int. J. Obes. Relat. Metab. Disord., 27(8): 869-74, ABSTRACT (Applicant should note that only the abstract has been supplied, as the Examiner was unable to obtain a full copy of the reference in time for mailing with this Official Action)). Furthermore, in the case of insulin and STZ-induced

diabetes, Lukic demonstrates that the susceptibility of the mice is strain-specific, and depends on levels of IL-2, IFN-gamma, and TNF-alpha (Lukic, et al. (1998) Dev. Immunol., 6(1-2): 119-28, ABSTRACT (Applicant should note that only the abstract has been supplied, as the Examiner was unable to obtain a full copy of the reference in time for mailing with this Official Action)). Hence, if the susceptibility is strain-specific, it could not be reasonably predictive of treatment in other animals, much less humans. Similar argument has been previously submitted to Applicant (e.g., Official Action of 12/18/02, pp. 9-14).

Moreover, in addition to the fact that such SZT-induced diabetes occurs through different mechanisms than that which causes diabetes in the real world, Applicant's transformed cells are only temporarily transformed, and expression of transgenes is not expected to last for a long enough period of time to effect prophylactic treatment. For example, Eck, et al. (1996) Goodman & Gilman's The Pharmacological Basis of Therapeutics, 9th Ed., McGraw-Hill, New York, NY., pp. 77-101, p. 82, col. 1, paragraph 2, states that long-term gene expression is not guaranteed. In fact, it is not reasonable predicted to occur, because, in the case of non-integrating vectors, the vector may be lost, and in the case of integrating vectors, the production may decline due to inactivation of the transgene or immune responses (Id.).

With regard to non-endocrine cells and stem cells releasing insulin and/or leptin, it is not reasonably predictable that non-endocrine cells could deliver such insulin/leptin to the bloodstream to deliver a systemic effect as would be required of such treatments, as only endocrine cells perform this function (e.g., U.S. Patent No. 5,837,693, col. 2, paragraph 8; col. 3, paragraph 7).

Hence, to determine what disorders could be treated, either in prophylactic or therapeutic modes, in which animals, with which vectors, to induce a long enough and high enough amounts of protein, and using which cells, would require undue experimentation, in addition to the previously mentioned areas of undue experimentation (e.g., Official Action of 12/18/02, pp. 11-14). Therefore, the aforementioned scope of enablement is found.

Art Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-34, 36, 38, 40, 43, 47-50, and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,837,693 to German, et al., filed 3/24/95, patented 11/17/98.

With regard to Claim 31-34, 36, and 47-50, German teaches genetically-altered secretory gland cells which are genetically altered to incorporate a gene which expresses a protein, for the treatment of diseases which are amenable to treatment by expression of the protein (ABSTRACT). One disease which may treated is diabetes, by the expression of insulin and its secretion into the gastrointestinal tract (cols. 8-9, paragraph bridging; col. 10, paragraph 2). Moreover, because cells of the gastrointestinal tract are required for such secretion (Id.), and German teaches mucosal secretion (Id.), the mucosal cells of the gastrointestinal tract are taught.

Furthermore, German teaches promoters inducible by external agents (col. 4, paragraph 3) and gut endocrine promoters, as these would be used in secretory cells and is used for secretion of insulin into the blood (col. 4, paragraph 4). Moreover, such cells may be endocrine cells, as such would be required for such secretion (Id.). Lastly, it is inherent that the cells would be contacted with sugars, fats, carbohydrates, starch, amino acids, and polypeptides, as these cells are in the gastrointestinal tract, and during the normal course of feeding the animals, such cells would be so contacted.

With regard to Claim 35, German teaches levels of glucose higher than 110mg/dl (TABLE 6).

With regard to Claims 38-40, it is inherent that the sugars, fats, starch, amino acids and polypeptides to which the cells are exposed increases production of the insulin, as they provide the building blocks with which the insulin is made and the energy required to secrete it.

With regard to Claim 43, German teaches that the minimal promoter required is the minimal sequence sufficient to direct transcription (col. 4, paragraph 3).

With regard to Claim 54-55, the cells may be transformed with a viral vector comprising the promoter and insulin-encoding polynucleotide (col. 5, paragraphs 3-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 31, 43-44, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,837,693 to German, et al., filed 3/24/95, patented 11/17/98 and Boylan, et al. (1997) J. Biol. Chem., 272(28): 17438-43.

With regard to Claims 31 and 43, German teaches genetically-altered secretory gland cells which are genetically altered to incorporate a gene which expresses a protein, for the treatment of diseases which are amenable to treatment by expression of the protein (ABSTRACT). One disease which may treated is diabetes, by the expression of insulin and its secretion into the gastrointestinal tract (cols. 8-9, paragraph bridging; col. 10, paragraph 2). Moreover, because cells of the gastrointestinal tract are required for such secretion (Id.), and German teaches mucosal secretion (Id.), the mucosal cells of the gastrointestinal tract are taught. Furthermore, German teaches promoters inducible by external agents (col. 4, paragraph 3) and gut endocrine promoters, as these would be used in secretory cells and is used for secretion of insulin into the blood (col. 4, paragraph 4). Moreover, such cells may be endocrine cells, as such would be required for such secretion (Id.). Furthermore, it is inherent that the cells would be contacted with sugars, fats, carbohydrates, starch, amino acids, and polypeptides, as these cells are in the gastrointestinal tract, and during the normal course of feeding the animals, such cells would be so contacted. With regard to Claim 43, German teaches that the minimal promoter required is the minimal sequence sufficient to direct transcription (col. 4, paragraph 3).

However, German does not teach the use of the GIP promoter.

On the other hand, Boylan teaches the structure of the GIP promoter (ABSTRACT) and that such promoter is responsive to glucose levels, particularly in K-cells of the duodenum and proximal jejunum (p. 17438, col. 1, paragraph 1, after the abstract).

Therefore, at the time of invention by Applicant, it would have been obvious to modify the method of German by transforming K-cells of the duodenum with a polynucleotide encoding insulin, operably linked to the GIP promoter, as taught by Boylan. The Artisan would have been motivated to do so in order to secrete insulin in response to glucose, as taught by both German and Boylan. Moreover, the Artisan would have had a reasonable expectation of success, as German had taught that cells of the intestine could be used, along with inducible promoters, and Boylan had provided the GIP promoter required for such inducible production.

Claims Free of the Art of Record

Claims 39, 54-55, and 71-86 are free of the prior art of record.

Specifically, Claims 39, 54-55, 74 and 83-84 are drawn to non-endocrine cells and stem cells used in treating insulin/leptin-requiring treatments. However, the art of record of does not

contemplate such cells, but in fact contemplates the use of endocrine cells, e.g., U.S. Patent No. 5,837,693, col. 2. Moreover, such endocrine cells would be required for the secretion of such insulin into the blood system (enablement rejection).

Claims 71-86 are drawn to the treatment of leptin-requiring disorders. WO 96/25487 to Thorens, filed 2/7/96, published 8/22/96 is the closest art of record. However, Thorens only teaches that such systems should be useful for treating obesity, but does not provide the reasonable prediction of success required (p. 13, last paragraph-p. 14, first paragraph).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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